Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: June 27, 2011

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

AG

SUBJECT: Endo Pharmaceuticals Recall

SUGGESTED ACTION:

Unclassified Recall; Endocet® (oxycodone/acetaminophen, USP) Tablets, 10 mg/325 mg 100 count bottles, NDC 60951-712-70, Lot # 402415NV and #402426NV. One bottle from each lot of Endocet® (oxycodone/acetaminophen, USP) Tablets, 10 mg/325 mg, Lot # 402415NV and # 402426NV, NDC 60951-712-70, 100 count bottles, was found to contain some Endocet® 10 mg/650 mg Tablets; Information is provided in case of consumer inquiry.

From the information provided by FDA, the products being recalled were distributed in the neighboring States of Ohio Illinois and Kentucky. These lots were distributed between April 19, 2011 and May 10, 2011 directly to wholesalers who are located in the following states: AL, AZ, CA, CO, NY, OH, ND, PR, IL, KY, NH, NJ, LA, NC, MO, PA, FL and TN. These wholesalers may further distribute to other retailers and wholesalers nationwide.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Endo Pharmaceuticals Issues Voluntary, Nationwide Recall of Two Lots of Endocet® (Oxycodone/Acetaminophen, USP) Tablets, 10 MG / 325 MG

Contact:
Consumer:
1-866-723-2681

Media:
Kevin Wiggins
610-459-7281

FOR IMMEDIATE RELEASE - June 24, 2011 - Endo Pharmaceuticals today issued a voluntary nationwide consumer level recall of **Endocet® (oxycodone/acetaminophen, USP) Tablets, 10 mg/325 mg 100 count bottles, NDC 60951-712-70, Lot # 402415NV and #402426NV**. One bottle from each lot of Endocet® (oxycodone/acetaminophen, USP) Tablets, **10 mg/325 mg, Lot # 402415NV and # 402426NV, NDC 60951-712-70**, 100 count bottles, was found to contain some Endocet® 10 mg/650 mg Tablets, which are identifiable by their larger size, and different shape and markings. Currently, no other bottles from the subject lots or any other lots have been found to erroneously contain Endocet® 10 mg/650 mg Tablets.

No injuries have been reported to date.

Because the recalled bottles may contain incorrect tablets that have a higher dosage of acetaminophen, consumers may take more than the intended acetaminophen dose. Unintentional administration of tablets with increased acetaminophen content may result in liver toxicity, especially in patients on other acetaminophen containing medications, patients with liver dysfunction, or people who consume more than 3 alcoholic beverages a day. The product label warns consumers that acetaminophen overdosage can potentially cause severe liver damage.

Consumers who have the affected product should stop using the product and contact **Endo's agent Stericycle at 1-866-723-2681** for return of the product. If consumers have any questions as to whether they possess the affected product, please call the number listed above.

The recall includes the following lots of this product:

- Endocet® (oxycodone/acetaminophen, USP) Tablets, 10 mg /325 mg 100 count bottles, NDC 60951-712-70, Lot # 402415NV, Expiry 01/2014; and
- Endocet® (oxycodone/acetaminophen, USP) Tablets, 10 mg /325 mg 100 count bottles, NDC 60951-712-70,Lot # 402426NV, Expiry 01/2014

This voluntary recall is being made with the knowledge of the U.S. Food and Drug Administration.

These lots were distributed between April 19, 2011 and May 10, 2011 directly to wholesalers who are located in the following states: AL, AZ, CA, CO, NY, OH, ND, PR, IL, KY, NH, NJ, LA, NC, MO, PA, FL and TN. These wholesalers may further distribute to other retailers and wholesalers nationwide. Lot numbers can be found on the side of the manufacturer's bottle.

Endocet® (oxycodone/acetaminophen, USP) 10 mg/325 mg tablets are 0.6 inches in length, 0.27 inches in width and yellow capsule-shaped tablets, marked "E712" on one side and "10/325" on the other. By contrast, Endocet® (oxycodone/acetaminophen, USP) 10 mg/650 mg tablets are larger (0.7 inches in length, 0.4 inches in width) and yellow oval-shaped tablets, marked "E797" on one side and "10"on the other.

Endo is notifying all customers who may have received affected product and arranging for the return of any affected product.

Consumers with questions may contact **Endo's agent Stericycle at 1-866-723-2681** during the hours of 8AM – 8PM EST Monday through Friday and 8AM – 5PM EST Saturday and Sunday. The phones will be staffed by Stericycle.

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either on line, by regular mail, or by fax.

- **Online:** www.fda.gov/medwatch/report.htm[1]
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[2]. Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

Reports of adverse reactions or quality problems can also be reported to Endo Pharmaceuticals at 1-800-462-3636.

About Endo Pharmaceuticals

Endo Pharmaceuticals is a U.S.-based, specialty healthcare solutions company, focused on high-value branded products and specialty generics. Endo is redefining its position in the healthcare marketplace by anticipating and embracing the evolution of health decisions based on the need for high-quality and cost-effective care. We aim to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of complementary diagnostics, drugs, devices and clinical data to meet the needs of patients in areas such as pain, urology, oncology and endocrinology. For more information about Endo Pharmaceuticals, and its wholly owned subsidiaries American Medical Systems, Inc., HealthTronics, Inc. and Qualitest Pharmaceuticals, please visit http://www.endo.com/[3].

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